

K971833

JUN - 2 1997

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**1) Submitter
name, address,
contact**

Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: LeeAnn Chambers

Date Prepared: May 15, 1997

2) Device name

Proprietary name: Elecsys® Ferritin

Common name: Ferritin immunological test system

Classification name: Ferritin immunological test system

**3) Predicate
device**

We claim substantial equivalence to Enzymun-Test® Ferritin.

**4) Device
Description**

The Elecsys® Ferritin employs a sandwich test principle with monoclonal antibodies directed against ferritin and with streptavidin microparticles and electrochemiluminescence detection.

Total duration of assay: 18 minutes.

- 1st Incubation: 15 µl of sample a biotinylated monoclonal ferritin-specific antibody and a monoclonal ferritin-specific antibody labeled with a ruthenium complex react to form a sandwich complex.
 - 2nd Incubation: after the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
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510(k) Summary, Continued

4) Device Description

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
 - Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent bar code.
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5) Intended use

Immunoassay for the in vitro quantitative determination of ferritin in human serum and plasma.

6) Comparison to predicate device

The Boehringer Mannheim Elecsys Ferritin is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Enzygnost Ferritin.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. LeeAnn Chambers, RAC
Program Manager, Regulatory Affairs
Boehringer Mannheim Corporation
Regulatory Affairs
Quality System and Compliance
9115 Hague Road
Indianapolis, Indiana 46250

JUN - 2 1997

Re: K971833
Trade Name: Elecsys® Ferritin
Regulatory Class: II
Product Code: JMG
Dated: May 15, 1997
Received: May 19, 1997

Dear Ms. Chambers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

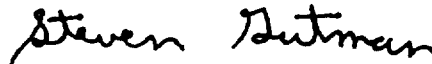
Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical

Laboratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

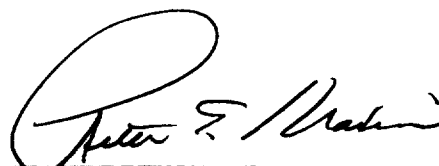
Enclosure

510(k) Number (if known):

Device Name: Elecsys® Ferritin

Indications for Use:

Immunoassay for the in vitro quantitative determination of ferritin in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Boehringer Mannheim Elecsys 2010 immunoassay analyzer.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format I-2-96)